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What is claimed is:

1. A pharmaceutical composition comprising micronized eplerenone in an amount of about 10 mg to about 1000 mg and a pharmaceutically acceptable carrier material.

2. The pharmaceutical composition according to claim 1 wherein said composition comprises micronized eplerenone in an amount of about 20 mg to about 400 mg.

3. The pharmaceutical composition according to claim 1 wherein said composition comprises micronized eplerenone in an amount of about 25 mg to about 150 mg.

4. The pharmaceutical composition according to claim 1 wherein said composition comprises micronized eplerenone in an amount of about 25 mg to about 100 mg.

5. The pharmaceutical composition according to claim 1 wherein said carrier material is cellulosic, and said cellulosic carrier material is selected from the group consisting of purified cellulose, microcrystalline cellulose, and alkyl celluloses and their derivatives and salts.

6. The pharmaceutical composition according to claim 1 comprising one or more pharmaceutically acceptable binding agents, wherein

said binding agent or binding agents are present at about 0.5% to about 25% of the total weight of the composition.

7. The pharmaceutical composition according to claim 6 wherein said binding agents are selected from the group consisting of acacia, tragacanth, sucrose, gelatin, glucose, starch, celluloses, alginic acid, salts of alginic acid, magnesium aluminum silicate, polyethylene glycol, gums, polysaccharide acids, bentonites, polyvinylpyrrolidone, polymethacrylates, hydroxypropyl methylcellulose, hydroxypropyl cellulose, ethyl cellulose, and pregelatinized starch.

8. The pharmaceutical composition according to claim 1 comprising one or more pharmaceutically acceptable diluents, wherein said diluent or diluents are present at about 5% to about 99% of the total weight of the composition.

9. The pharmaceutical composition according to claim 8 wherein said diluents are selected from the group consisting of lactose, starch, mannitol, sorbitol, dextrose, microcrystalline cellulose, dibasic calcium phosphate, sucrose-based diluents, confectioner's sugar, monobasic calcium sulfate monohydrate, calcium sulfate dihydrate, calcium lactate trihydrate, dextrates, inositol, hydrolyzed cereal solids,

amylose, powdered cellulose, calcium carbonate, glycine, and bentonite.

10. The pharmaceutical composition according to claim 1 comprising one or more pharmaceutically acceptable disintegrants, wherein said disintegrants are present at about 0.5% to about 30% of the total weight of the composition.

11. The pharmaceutical composition according to claim 10 wherein said disintegrants are selected from the group consisting of starches, sodium starch glycolate, clays, celluloses, alginates, pregelatinized corn starches, crospovidone, and gums.

12. The pharmaceutical composition according to claim 1 comprising one or more pharmaceutically acceptable wetting agents, wherein said wetting agents or wetting agents are present at about 0.1% to about 15% of the total weight of the composition.

13. The pharmaceutical composition according to claim 12 wherein said wetting agents are selected from the group consisting of oleic acid, glyceryl monostearate, sorbitan mono-oleate, sorbitan monolaurate, triethanolamine oleate, polyoxyethylene sorbitan mono-oleate, polyoxyethylene sorbitan monolaurate, sodium oleate, and sodium lauryl sulfate.

14. The pharmaceutical composition according to claim 1 comprising one or more pharmaceutically acceptable lubricants, wherein said lubricant or lubricants are present at about 0.1% to about 10% of the total weight of the composition.

15. The pharmaceutical composition according to claim 14 wherein said lubricants are selected from the group consisting of glyceryl behenate, stearates, stearic acid, hydrogenated vegetable oils, talc, waxes, Stearowet, boric acid, sodium benzoate, sodium acetate, sodium chloride, DL-Leucine, polyethylene glycols, sodium oleate, sodium lauryl sulfate, and magnesium lauryl sulfate. stearate.

16. The pharmaceutical composition according to claim 1 comprising one or more pharmaceutically acceptable anti-adherents or glidants, wherein said anti-adherent or anti-adherents or glidants are present at about 0.25% to about 10% of the total weight of the composition.

17. The pharmaceutical composition according to claim 16 wherein said anti-adherents or glidants are selected from the group consisting of talc, cornstarch, DL-Leucine, sodium lauryl sulfate, and metallic stearates.

18. The pharmaceutical composition according to claim 6 wherein said micronized eplerenone is present at about 1% to about 90% of the total weight of the composition.

19. The pharmaceutical composition according to claim 18 comprising one or more carrier materials selected from the group consisting of diluents, binding agents, disintegrants, wetting agents, lubricants and anti-adherents or glidants.

20. The pharmaceutical composition according to claim 18 comprising hydroxypropyl methylcellulose.

21. The pharmaceutical composition according to claim 18 comprising lactose.

22. The pharmaceutical composition according to claim 18 comprising microcrystalline cellulose.

23. The pharmaceutical composition according to claim 18 comprising croscarmellose sodium.

24. The pharmaceutical composition according to claim 1 comprising:

lactose at about 5% to about 90% of the total weight of the composition;

microcrystalline cellulose at about 5% to about 90% of the total weight of the composition; and

hydroxypropyl methylcellulose at about 0.5% to about 10% of the total weight of the composition.

25. The pharmaceutical composition according to claim 1 comprising:

about 1 to about 90 weight percent of micronized eplerenone;

about 5 to about 90 weight percent of lactose;

about 5 to about 90 weight percent of microcrystalline cellulose; and

about 0.5 to about 10 weight percent of hydroxypropyl methylcellulose.

26. The pharmaceutical composition according to claim 1 comprising:

about 19 to about 40 weight percent of micronized eplerenone;

about 32 to about 52 weight percent of lactose;

about 8 to about 28 weight percent of microcrystalline cellulose; and

about 1 to about 8 weight percent of hydroxypropyl methylcellulose.

27. The pharmaceutical composition according to claim 1 comprising:

about 24 to about 35 weight percent of micronized eplerenone;

about 37 to about 47 weight percent of lactose;

about 13 to about 23 weight percent of microcrystalline cellulose;

about 2 to about 6 weight percent of croscarmellose sodium; and

about 2 to about 4 weight percent of hydroxypropyl methylcellulose.

28. The pharmaceutical composition according to claim 1 comprising:

about 28 to about 31 weight percent of micronized eplerenone;

about 41 to about 43 weight percent of lactose monohydrate;

about 17 to about 19 weight percent of microcrystalline cellulose;

about 4.5 to about 5.5 weight percent of croscarmellose sodium; and

about 2.5 to about 3.5 weight percent of hydroxypropyl methylcellulose.

29. The pharmaceutical composition according to claim 1 in the form of a coated or uncoated unit dosage tablet wherein the uncoated tablet or the coated tablet prior to coating comprises:

about 29.4 weight percent of micronized eplerenone;

about 42 weight percent of lactose;

about 18.1 weight percent of microcrystalline cellulose;

about 5 weight percent of croscarmellose sodium;

about 3 weight percent of hydroxypropyl methylcellulose;

about 1 weight percent of sodium lauryl sulfate;

about 1 weight percent of talc; and

about 0.5 weight percent of magnesium stearate.

30. The pharmaceutical composition according to claim 1 comprising:

about 23 mg to about 27 mg of micronized eplerenone;

about 34 mg to about 38 mg of lactose;

about 14 mg to about 17 mg of microcrystalline cellulose;

about 3 mg to about 6 mg of croscarmellose sodium;

about 1 mg to about 4 mg of hydroxypropyl methylcellulose;

about 0.25 mg to about 1.5 mg of sodium lauryl sulfate;

about 0.25 mg to about 1.5 mg of talc; and

about 0.1 mg to about 1 mg of magnesium stearate.

31. The pharmaceutical composition according to claim 1 comprising:

about 48 mg to about 52 mg of micronized eplerenone;

about 70 mg to about 73 mg of lactose;

about 29 mg to about 33 mg of microcrystalline cellulose;

about 6 mg to about 10 mg of croscarmellose sodium;

about 4 mg to about 6 mg of hydroxypropyl methylcellulose;

about 1 to about 2.5 mg of sodium lauryl sulfate;

about 1 to about 2.5 mg of talc; and

about 1 mg to about 1.5 mg of magnesium stearate.

32. The pharmaceutical composition according to claim 1 comprising:

about 98 mg to about 102 mg of micronized eplerenone;

about 141 mg to about 145 mg of lactose;

about 60 mg to about 64 mg of microcrystalline cellulose;

about 16 mg to about 18 mg of croscarmellose sodium;

about 9 mg to about 11 mg of hydroxypropyl methylcellulose;

about 3 mg to about 4 mg of sodium lauryl sulfate;

about 3 mg to about 4 mg of talc; and

about 1 mg to about 2 mg of magnesium stearate.

33. The pharmaceutical composition according to claim 1 in a unit oral dosage form.

34. The pharmaceutical composition according to claim 1, wherein said composition is in the form of a unit dosage tablet or capsule.

35. The pharmaceutical composition according to claim 1, wherein said composition is in the form of a unit dosage tablet.

36. The pharmaceutical composition according to claim 35 wherein the unit dosage tablet is a coated unit dosage tablet.

37. The pharmaceutical composition according to claim 1 in the form of an oral unit dosage tablet or capsule having a 25 mg, 50 mg or 100 mg dose of eplerenone.

38. A pharmaceutical composition comprising micronized eplerenone and β-cyclodextrin in a liquid dosage form.

39. A pharmaceutical composition comprising micronized eplerenone and a pharmaceutical carrier material, wherein said composition is suitable for once or twice a day oral administration as an aldosterone receptor blocker.

40. The pharmaceutical composition according to claim 1 wherein said composition provides a therapeutic effect as an aldosterone receptor blocker in a human subject over an interval of about 12 to about 24 hours after ingestion.

41. The pharmaceutical composition according to claim 1 wherein said composition provides a therapeutic effect as an aldosterone receptor blocker over an interval of about 24 hours after ingestion.

42. The pharmaceutical composition according to claim 1 wherein at least 50% of the eplerenone in the composition is released *in vitro* within 20 minutes in 0.1 N HCl.

43. The pharmaceutical composition according to claim 42 in the form of an oral dosage tablet or capsule suitable for once or twice a day oral administration.

44. The pharmaceutical composition according to claim 1 in the form of an oral dosage tablet or capsule suitable for once a day oral administration, and wherein at least 50% of the micronized eplerenone in the composition is released *in vitro* within 15 minutes in 0.1 N HCl.

45. The unit oral dosage form of the pharmaceutical composition of claim 33 wherein the

composition is directly encapsulated or directly compressed into tablets.

46. The unit oral dosage form of the pharmaceutical composition of claim 33 wherein the composition is wet granulated and encapsulated or compressed into tablets.

47. The unit oral dosage form of the pharmaceutical composition of claim 33 wherein the composition is dry granulated and encapsulated or compressed into tablets.

48. The pharmaceutical composition according to claim 1 wherein at least 90% of the micronized eplerenone particles used in the preparation of the pharmaceutical composition are less than about 200 microns in size.

49. The pharmaceutical composition according to claim 1 wherein at least 90% of the eplerenone particles used in the preparation of the pharmaceutical composition are less than about 150 microns in size.

50. The pharmaceutical composition according to claim 1 wherein at least 90% of the eplerenone particles used in the preparation of the pharmaceutical composition are about 30 to about 110 microns in size.

51. The pharmaceutical composition according to claim 1 wherein at least 90% of the eplerenone particles used in the preparation of the pharmaceutical composition are about 30 to about 50 microns in size.

52. The pharmaceutical composition according to claim 1 wherein at least 90% of the eplerenone particles used in the preparation of the pharmaceutical composition are about 50 to about 150 microns in size.

53. The pharmaceutical composition according to claim 1 wherein at least 90% of the eplerenone particles used in the preparation of the pharmaceutical composition are about 75 to about 125 microns in size.

54. A pharmaceutical composition comprising micronized eplerenone and a pharmaceutically acceptable carrier material, wherein said composition causes an average increase in blood serum renin concentrations in a human subject over an interval of about 12 to 24 hours after ingestion of the composition of at least about 10%.

55. A pharmaceutical composition comprising micronized eplerenone and a pharmaceutically acceptable carrier material, wherein said composition causes an average increase in blood serum aldosterone concentrations in a human subject

over an interval of about 12 to 24 hours after ingestion of the composition of at least about 50%.

56. A pharmaceutical composition comprising micronized eplerenone and a pharmaceutically acceptable carrier material, wherein said composition causes an average decrease in diastolic blood pressure in a human subject over an interval of about 12 to 24 hours after ingestion of the composition of at least about 5%.

57. The method of treating a condition or disorder where treatment with an aldosterone receptor blocker is indicated, comprising orally administering a composition according to claim 1 to a patient in need of such treatment.

58. The method according to claim 57 wherein the condition or disorder is heart failure.

59. The method according to claim 57 wherein the condition or disorder is hypertension.

60. The method according to 57 wherein the condition or disorder is edema associated with liver insufficiency.

61. The method according to claim 57 wherein the condition or disorder is post-myocardial infarction.

62. The method of treating a condition or disorder where treatment with an aldosterone receptor blocker is indicated, comprising orally administering a composition according to claim 18 to a patient in need of such treatment.

63. The method of treating a condition or disorder where treatment with an aldosterone receptor blocker is indicated, comprising orally administering a composition according to claim 26 to a patient in need of such treatment.

64. A method of preparing a pharmaceutical composition comprising eplerenone comprising:

wet granulating micronized eplerenone and one or more carrier materials to form a wet granulated mixture; and

preparing an oral dosage form of the pharmaceutical composition from the wet granulated mixture.

65. The method of claim 64 wherein the pharmaceutical composition is prepared in an oral unit dosage form comprising micronized eplerenone in an amount of about 25 mg, 50 mg or 100 mg.

66. Use of micronized eplerenone and a cellulosic carrier material in the manufacture of a medicament for the treatment or prophylaxis of aldosterone mediated conditions or disorders.

67. A pharmaceutical composition comprising micronized eplerenone and a pharmaceutically acceptable carrier material, wherein said composition is an oral dosage form in which at least 50% of the eplerenone in the composition is released *in vitro* at least about 1.5 hours in 1% SDS.

68. The pharmaceutical composition according to claim 67 comprising:

about 24 to about 35 weight percent of micronized eplerenone;

about 25 to about 45 weight percent of lactose;

about 10 to about 25 weight percent of microcrystalline cellulose; and

about 5 to about 50 weight percent of hydroxypropyl methylcellulose.

69. A pharmaceutical composition comprising micronized eplerenone and a pharmaceutically acceptable carrier material, wherein said composition is an oral dosage form wherein at least 50% of the micronized eplerenone in the composition is released *in vitro* at least about 3.5 hours in 1% SDS.

70. The pharmaceutical composition according to claim 69 comprising:

about 24 to about 35 weight percent of micronized eplerenone;

about 25 to about 45 weight percent of lactose;

about 10 to about 25 weight percent of microcrystalline cellulose; and

about 5 to about 50 weight percent of hydroxypropyl methylcellulose.

71. A pharmaceutical composition comprising micronized eplerenone and a pharmaceutically acceptable carrier material, wherein said composition is an oral dosage form wherein at least 50% of the micronized eplerenone in the composition is released *in vitro* at least about 5.5 hours in 1% SDS.

72. The pharmaceutical composition according to claim 71 comprising:

about 24 to about 35 weight percent of micronized eplerenone;

about 25 to about 45 weight percent of lactose;

about 10 to about 25 weight percent of microcrystalline cellulose; and

about 5 to about 50 weight percent of hydroxypropyl methylcellulose.